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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1655

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,555

Applicant(s)

STUELPNAGEL ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18-27 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-27 and 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. This action is in response to papers filed 10 December 2001 in Paper No. 8 in which claims 1, 3, 19 and 20 were amended, claims 13-17 and 28-43 were canceled and claims 28-31 were added. New claims 28-31 have been renumbered 44-47 under 37 C.F.R. 1.126. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 6 dated 20 April 2001 are withdrawn in view of new grounds for rejection. All of the arguments have been thoroughly reviewed but are deemed moot in view of the withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Currently claims 1-12, 18-27 and 44-47 are under prosecution.

Specification

2. The disclosure is objected to because of the following informalities: The first paragraph of the specification does not recite Applicant's claim to priority of the Provisional Application 60/119,323, filed 02/09/1999.

Appropriate correction is required.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The Provisional Application filed 9 February 1999 upon which priority is claimed does not provide adequate support under 35 U.S.C. 112 for the pending claims of the instant application. The instant claims are drawn to an array, array composition and method of making an array

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wherein the array comprises at least one fiducial. Provisional Application 60/119,323, does not disclose an array comprising at least one fiducial. Therefore, because the Provisional Application does not provide adequate support for the pending claims, the effective filing date for the pending claims is the filing date of the instant application i.e. 9 February 2000.

Information Disclosure Statement

4. The references listed on the 1449 of Paper No. 4, which were not supplied with the originally supplied references have been received and reviewed. A second copy of the 1449 of Paper No. 4 has been signed and is enclosed with this action.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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6. Claims 1-6, 8-10, 18-23, 25-27 and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al. (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

Regarding Claim 1, Walt et al. disclose an array composition comprising: a substrate with a surface comprising: discrete sites; a population of microspheres comprising at least a first and a second subpopulation wherein each subpopulation comprises a bioactive agent, wherein said microspheres are distributed on said surface (Column 3, lines 35-45) and wherein the array comprises at least one fiducial i.e. marker bead (Column 19, lines 2-5).

Regarding Claim 2, Walt et al. disclose the array wherein each subpopulation comprises a unique optical signature (Column 3, lines 40-42).

Regarding Claim 3, Walt et al. disclose the array wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated (Column 7, line 55-Column 8, lines 19).

Regarding Claim 4, Walt et al. disclose the array wherein said substrate is a fiber optic bundle (Column 5, lines 24-31) and the fiducial is a fiducial fiber i.e. fiber having a different diameter (Column 19, lines 13-15).

Regarding Claim 5, Walt et al. disclose the array wherein said substrate is a fiber optic bundle (Column 5, lines 24-31) and said array comprises at least three non-linear fiducials each of which is a fiducial fiber i.e. the fiducial fibers of differing size denote subarrays and the array of Walt et al. comprises at least three sub-arrays (Column 18, line 65-Column 19, line 2 and lines 13-15).

Regarding Claim 6, Walt et al. disclose the array wherein said fiducial has a different shape i.e. fiber having a different diameter (Column 19, lines 13-15).

Regarding Claim 8, Walt et al. disclose the array wherein the fiducial is a fiducial bead i.e. marker bead (Column 19, lines 2-5).

Regarding Claim 9, Walt et al. disclose the array wherein said bioactive agents are nucleic acids (Column 9, lines 41-43).

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Regarding Claim 10, Walt et al. disclose the array wherein said bioactive agents are proteins (Column 8, lines 35-38).

Regarding Claim 18, Walt et al. disclose a method of making an array composition comprising: forming a substrate with a surface comprising individual sites; and distributing microspheres on said surface such that said individual sites contain microspheres (Column 17, lines 11-53) wherein said microspheres comprise at least a first and a second subpopulation each comprising a bioactive agent (Column 3, lines 35-45) and incorporating at least one fiducial (Column 19, lines 2-5).

Regarding Claim 19, Walt et al. disclose the method wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated (Column 7, line 55-Column 8, lines 19).

Regarding Claim 20, Walt et al. disclose the method wherein each subpopulation comprises a unique optical signature for identification and elucidation of the bioactive agent (Column 13, lines 8-24).

Regarding Claim 21, Walt et al. disclose the method wherein said substrate is a fiber optic bundle (Column 5, lines 24-31) and the fiducial is a fiducial fiber i.e. fiber having a different diameter (Column 19, lines 13-15).

Regarding Claim 22, Walt et al. disclose the method wherein said substrate is a fiber optic bundle (Column 5, lines 24-31) and said array comprises at least three non-linear fiducials each of which is a fiducial fiber i.e. the fiducial fibers of differing size denote subarrays and the array of Walt et al. comprises at least three sub-arrays (Column 18, line 65-Column 19, line 2 and lines 13-15).

Regarding Claim 23, Walt et al. disclose the method wherein said fiducial has a different shape i.e. fiber having a different diameter (Column 19, lines 13-15).

Regarding Claim 25, Walt et al. disclose the method wherein the fiducial is a fiducial bead i.e. marker bead (Column 19, lines 2-5).

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Regarding Claim 26, Walt et al. disclose the method wherein said bioactive agents are nucleic acids (Column 9, lines 41-43).

Regarding Claim 27, Walt et al. disclose the method wherein said bioactive agents are proteins (Column 8, lines 35-38).

Regarding Claim 44, Walt et al. disclose the array of Claim 1 wherein said discrete sites are wells (Column 17, lines 38-46).

Regarding Claim 45, Walt et al. disclose the array of Claim 1 wherein the microspheres are randomly distributed on said substrate (Column 17, lines 47-53).

Regarding Claim 46, Walt et al. disclose the method of Claim 18 wherein said discrete sites are wells (Column 17, lines 38-46).

Regarding Claim 47, Walt et al. disclose the method of Claim 18 wherein the microspheres are randomly distributed on said substrate (Column 17, lines 47-53).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Augenlicht (U.S. Patent No. 4,981,783).

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Regarding Claim 7, Walt et al. teach an array composition comprising: a substrate with a surface comprising discrete sites; a population of microspheres comprising at least a first and a second subpopulation wherein each subpopulation comprises a bioactive agent, wherein said microspheres are distributed on said surface (Column 3, lines 35-45) and wherein the array comprises at least one fiducial i.e. marker bead (Column 19, lines 2-5) wherein the marker bead denotes each subarray, but they do not specifically teach the fiducial is a defined edge of said substrate. Augenlicht teach similar array comprising a substrate comprising discrete sites; a population of bioactive agents comprising at least a first and second subpopulation of bioactive agents distributed on said surface; and at least one fiducial wherein said fiducial is a defined edge of said substrate wherein the fiducial placement facilitates automated detection and identification of the bioactive agent (Column 8, lines 15-26 and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the fiducial placement taught by Augenlicht to the array composition of Walt et al and to place the fiducials so as to define an edge of the array to thereby align the array for detection as taught by Augenlicht (Column 7, lines 33-35) for the expected benefit facilitating detection and identification of the bioactive agent as taught by Augenlicht (Column 8, lines 15-26).

Regarding Claim 24, Walt et al. teach a method of making an array composition comprising: forming a substrate with a surface comprising individual sites; and distributing microspheres on said surface such that said individual sites contain microspheres (Column 17, lines 11-53) wherein said microspheres comprise at least a first and a second subpopulation each comprising a bioactive agent (Column 3, lines 35-45) and incorporating at least one fiducial (Column 19, lines 2-5) wherein the marker bead denotes each subarray, but they do not specifically teach the fiducial is a defined edge of said substrate. Augenlicht teach similar method comprising: forming a substrate comprising discrete sites; a population of bioactive agents comprising at least a first and second subpopulation of bioactive agents distributed on said surface; and at least one fiducial wherein said fiducial is a defined edge of said substrate

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wherein the fiducial placement facilitates automated detection and identification of the bioactive agent (Column 8, lines 15-26 and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the fiducial placement taught by Augenlicht to the method of making an array composition of Walt et al and to place the fiducials to define an edge of the array to thereby align the array for detection as taught by Augenlicht (Column 7, lines 33-35) for the expected benefit facilitating detection and identification of the bioactive agent as taught by Augenlicht (Column 8, lines 15-26).

9. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Chee et al. (U.S. Patent No. 5,795,716, issued 18 August 1998).

Regarding Claim 11, Walt et al. teach an array composition comprising: a substrate with a surface comprising discrete sites; a population of microspheres comprising at least a first and a second subpopulation wherein each subpopulation comprises a bioactive agent, wherein said microspheres are distributed on said surface (Column 3, lines 35-45) and wherein the array comprises at least one fiducial i.e. marker bead (Column 19, lines 2-5). Additionally they teach the array is analyzed using a computer and computer software which strongly suggests that a computer code receives and registers data images (Column 16, lines 10-20 and 45-49) but they do not specifically teach a computer code receives and registers as first data image. Chee et al. teach an array composition comprising a substrate with a surface comprising discrete sites and a population of bioactive agents (Column 3, lines 34-47) and further comprising computerized analysis using a computer readable memory comprising: a

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computer code that receives a first data image; and a computer code that registers said first data image (Claim 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Walt et al. with the computer readable memory of Chee et al. and to use the fiducial to position-specifically receive and register a first data image via the computer code for the expected benefit of computer aided improved analysis of bioagents as taught by Chee et al. (Column 1, lines 55-67).

Regarding Claim 12, Chee et al. teach the computer readable memory further comprises a computer code that receives a second data image; a computer code that registers said second data image; and a computer code that compares said first and second data image (Claim 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further modify the array composition of Walt et al. with the computer readable memory further comprising a computer code that receives and registers a second data image and compares the first and second data images for the expected benefit of allowing image analysis and statistical analysis of multiple data files simultaneously as taught by Chee et al. (Column 22, lines 23-32).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

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application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1655
February 4, 2002